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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/036,418      | 01/07/2002  | Aaron I. Vinik       | 005126.00009        | 4672             |

27752 7590 12/29/2004

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EXAMINER

CHEU, CHANGHWA J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1641

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/036,418

**Applicant(s)**

VINIK ET AL.

**Examiner**

Jacob Cheu

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 15-23 and 38-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 24-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election on 10/20/2004 with traverse of group III, claims 24-37, is acknowledged. The traversal is on the ground(s) that both group I and III are for assaying the INGAP protein by using antibodies recognizing different epitopes on the INGAP protein. Therefore, the methods recited in group I and III share a common function. Examiner found this reason persuasive, accordingly group I and III, claims 1-14, 24-37 are rejoined for examination.

With respect to other group II and IV, both have features not required by the other, and the products recited in group II and IV can be used in a materially different process such as purification or isolation purposes.

The restriction is deemed proper and final.

Currently, claims 1-14, 24-37 are under examination. Claims 15-23, 38-46 are withdrawn from further consideration.

### ***Claim Rejections - 35 USC § 112***

#### **Scope of Enablement**

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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2. Claims 24-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for residues 139-152 (SEQ ID No. 3), 151-164 (SEQ ID No. 4), does not reasonably provide enablement for residues 104-118 (SEQ ID No. 2). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant invention directs a method of using INGAP specific antibody to detect a sample containing said INGAP protein. Applicant recited several antibody recognizable epitope amino acid residues, such as SEQ ID No. 1, 2, 3 and 4. However, applicant notes “that a peptide consisting of residues 104-118 (SEQ ID No. 2) did not successfully compete with full length INGAP for binding to the antibodies” (See Section 0017, Detailed Description of the Invention)(emphasis added). Furthermore, applicant indicates that “only INGAP 20-40 (SEQ ID No. 1) functions in this assay” (note comparing with residues 104-118, SEQ ID No. 2) (See Section 0056; Experiment 2; Figure 5)(emphasis added). Accordingly, the instant invention is entitled for the scope of residues SEQ ID No. 1, 3 and 4 only.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14, 24-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, INGAP needs to be spelled out for clarification.

With respect to claim 1, line 2, “bound antibodies with a test sample” is vague and indefinite. It is not clear whether these antibodies bind to the solid support or the test sample.

With respect to claim 1, line 4, “whereby INGAP protein in the test sample binds to the solid support” is vague and indefinite. It is not clear whether the INGAP protein should bind to the antibodies instead. Applicant needs to clarify.

With respect to claim 1, line 11-13, it is not clear why the labeled INGAP would bind to the solid support since the assay is based on competition where “unlabeled analyte (INGAP) in a sample competes with a labeled analyte for binding to the antibody” (See Section 0037).

With respect to claim 2, line 4, “the amount of marker protein” is vague and indefinite. It is not clear what is the relationship with the antibody or INGAP protein.

With respect to claim 8, it is not clear whether a separation step is required. If claim does not need a separation step, then how can one determine the reduction of the labeled due to competition.

With respect to claim 24, line 2, "bound antibodies with a test sample" is vague and indefinite. It is not clear whether these antibodies bind to the solid support or the test sample.

With respect to claim 31, it is not clear whether a separation step is required. If claim does not need a separation step, then how can one determine the reduction of the labeled due to competition.

***Allowable Subject Matter***

4. Claims 1-14 and 24-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter:

The instant claim recites a method using antibodies for detect INGAP protein in a test sample. Particularly, specific amino acid residues, such as SEQ ID No. 1, 3 and 4, as specific epitopes recognized by the antibodies are novel and unobvious. No prior art teaches or fairly suggests the above specific regions of amino acid as INGAP antibody epitopes. The closest prior art is the reference of Vinik et al. (US 5840531) where Vinik

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et al. disclose using antibodies recognizing different epitopes, i.e. around 174 amino acid residues versus 12-20 amino acid residues of the instant invention, on the INGAP to detect the INGAP protein.

#### Conclusion

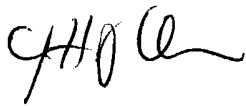
6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

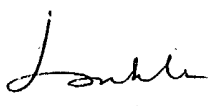
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu  
Examiner  
Art Unit 1641



December 14, 2004

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

12/26/04